

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/621,909	VACCARO ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Paper filed on Sep. 13, 2004 and Feb. 16, 2005.
2. ☒ The allowed claim(s) is/are 1-12, 14-17, 21 and 24-34.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>11/04, 04/05</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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### DETAILED ACTION

1. According to paper filed on Sep. 13, 2004, the applicants have canceled claims 13 and 19 and furthermore, have amended claims 1-4, 7, 8, 15, 17, 18, 20 and 24-27. In a subsequent amendment filed on Feb. 16, 2005, the applicants have canceled claims 18 and 20 and furthermore, have amended claims 1, 2, 6, 8-12, 15, 17 and 24-27.
2. Claims 1-12, 14-17 and 21-34 are now pending in the application.

### EXAMINER'S AMENDMENT

3. The following amendment is pursuant to a telephone conversation with the applicant's attorney, Ms. Laurelee A. Duncan on November 10, 2004. Although the applicant's attorney did not agree with the examiner regarding enablement rejection of method claims and the indefiniteness of prodrug esters yet in order to advance prosecution, the attorney agreed to cancel method claims and delete prodrug esters without prejudice to pursue this canceled subject matter in a divisional application. The following changes have been made in claims:

Cancel claims 18 and 20.

In claim 1, delete ---, or a prodrug ester thereof----

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In claim 24, delete ---, or a prodrug ester thereof----

In claim 25, delete ---, or a prodrug ester thereof----

In claim 26, delete ---, or a prodrug ester thereof----

In claim 27, delete ---, or a prodrug ester thereof----

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4. The following amendment is pursuant to a telephone conversation with the applicant's attorney, Ms. Laurelee A. Duncan on April 27, 2005. The following changes have been made in claims:

Cancel claims 22 and 23.

In claim 1, page 4, last seven lines, delete proviso II entirely and rewrite it as ----- provided that where Z is CH<sub>2</sub>NR<sub>1</sub>R<sub>2</sub> and where at least one of R<sub>1</sub> and R<sub>2</sub> is a heteroaryl selected from pyridinyl, pyrimidinyl, pyridazinyl, pyrazinyl or imidazoliny, then (a) the other of R<sub>1</sub> and R<sub>2</sub> is other than hydrogen, alkyl, alkenyl, cycloalkyl, alkylcycloalkyl, phenyl, alkylphenyl, phenylalkyl, monoalkylaminoalkyl, dialkylaminoalkyl, arylalkyl, aryl, alkoxyalkyl, or hydroxyalkyl, and/or (b) at least one of R<sub>a</sub>, R<sub>b</sub>, R<sub>c</sub> and/or R<sub>d</sub> is other than hydrogen or C<sub>1</sub>-2 alkyl, and/or (c) R is other than hydrogen or C<sub>1</sub>-C<sub>2</sub> alkyl and/or (d) one of R<sub>c</sub> and R<sub>d</sub> is other than hydroxyalkyl-----.

In claim 27, page 53, lines 3-9, delete this proviso entirely and rewrite it as --- provided that where at least one of R<sub>1</sub> and R<sub>2</sub> is a heteroaryl selected from pyridinyl, pyrimidinyl, pyridazinyl, pyrazinyl or imidazoliny, then (a) the other of R<sub>1</sub> and R<sub>2</sub> is other than hydrogen, alkyl, alkenyl, cycloalkyl, alkylcycloalkyl, phenyl, alkylphenyl, phenylalkyl, monoalkylaminoalkyl, dialkylaminoalkyl, arylalkyl, aryl, alkoxyalkyl, or hydroxyalkyl, and/or (b) at least one of R<sub>a</sub>, R<sub>b</sub>, R<sub>c</sub> and/or R<sub>d</sub> is other than hydrogen or C<sub>1</sub>-2 alkyl, and/or (c) R is other than hydrogen or C<sub>1</sub>-C<sub>2</sub> alkyl and/or (d) one of R<sub>c</sub> and R<sub>d</sub> is other than hydroxyalkyl-----.

REASONS FOR ALLOWANCE

5. The following is an examiner's statement of reasons for allowance:

Claims 1-12, 14-17, 21 and 24-34, renumbered as claims 1-28, are allowed since the applicants have amended claims to delete non-elected subject matter and to overcome enablement and indefiniteness rejections and furthermore, due to their persuasive arguments regarding remaining indefiniteness rejections. Thus, all rejections under 35 U.S.C. 112, first paragraph and second paragraph as well as objections are now withdrawn.

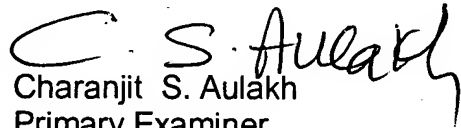
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625

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